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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,939	Applicant(s) STEER ET AL.	
	Examiner Rebecca E. Prouty	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 216-240 is/are pending in the application.
- 4a) Of the above claim(s) 218 and 221-240 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 216, 217, 219, 220 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/07, 7/06, 5/06, 10/05, 6/05, 4/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-215 have been canceled. Claims 216-240 are at issue and are present for examination.

Applicant's election with traverse of Group I (CB) drawn to methods of making a composition comprising a xylanase of SEQ ID NO:160 in the reply filed on 1/10/08 is acknowledged. The traversal is on the ground(s) that all pending claims have unity of invention as they share the novel inventive concept of use of a genus of polypeptides having xylanase activity that are active under a high temperature of at least 80°C and basic pH conditions of at least pH 10.5, or alternatively, use of a genus of polypeptides having xylanase activity that are active under a high temperature of at least 85°C and basic pH conditions of at least pH 11. This is not found persuasive because use of a genus of polypeptides having xylanase activity that are active under a high temperature of at least 80°C and basic pH conditions of at least pH 10.5, or alternatively, temperature of at least 85°C and basic pH conditions of at least pH 11 is not a special technical feature as defined by PCT Rule 13.2 as it is not novel over the art. Bodie et al (US Patent 5,437,992) teach use of several xylanases that are active under a high temperature of at least 80°C and basic pH conditions of at least pH 10.5, or alternatively, temperature of at least 85°C and basic pH conditions of at least pH 11. As such the instant

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claims do not share unity of invention and restriction as indicated is proper.

Applicants further argue they should be allowed to claim the generic methods of claims 216 and 217, and not be forced to incorporate unwanted limitations, i.e., be forced to incorporate a specific xylanase polypeptide. However, it is noted that Claims 216 and 217 ARE being examined with the in the instant application and applicants are NOT being forced to incorporate unwanted limitations. Claims 216 and 217 are linking claims which link at least some of the polypeptides recited in claims 219 and 220 (note many of polypeptides recited in these dependent claims are improperly included as Table 6 of specification shows that they clearly DO NOT have the recited temperature and pH activities recited in claims 216 and 217). The restriction requirement between any such linked inventions is **subject to** the nonallowance of the linking claim(s), claim 216 and 217. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a

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matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. However, at the present time the linking claims are NOT allowable and thus the restriction is maintained. Note if at any time the linking claims are found to be allowable applicants will have the opportunity to submit dependent claims reciting any of the restricted species which are within the scope of the allowable linking claim. Note however this does not include the entire list recited in claims 219 and 220 for the reasons presented above.

The requirement is still deemed proper and is therefore made FINAL.

Claims 218 and 221-240 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/10/08.

Claims 219 and 220 are objected to as reciting non-elected subject matter.

Claims 216, 217, 219, and 220 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The application as filed does not provide support for the current recitation of "active under conditions comprising a temperature of at least 85°C and a basic pH of at least pH 11" in claim 216 and "active under conditions comprising a temperature of at least 80°C and a basic pH of at least pH 10.5" [emphasis added]. While the specification individually provides support for xylanases active under temperatures of 85°C or 80°C and xylanases active under pH

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conditions of pH 11 or pH 10.5 it does not provide support for the combinations of pH and temperature conditions recited in the instant claims. Furthermore Table 6 of the specification does not provide support for the inclusion of the xylanase of SEQ ID NO:160 within these genera. Table 6 indicates that that the xylanase of SEQ ID NO:160 is stable to 85°C for less than 30 sec and no indication that this was measured at a high pH. As such this enzyme does not in fact appear to have the recited characteristics.

Claims 216, 217, 219 and 220 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 219 and 220 are confusing in the recitation of the xylanase of SEQ ID NO:160 as within the group of xylanases active under conditions comprising a temperature of at least 85°C and a basic pH of at least pH 11 in claim 216 and active under conditions comprising a temperature of at least 80°C and a basic pH of at least pH 10.5 in claim 217 as Table 6 indicates that that the xylanase of SEQ ID NO:160 is stable to 85°C for less than 30 sec and no indication that this was measured at a high pH. As such this enzyme does not in fact appear to have the recited characteristics. Note Table 6 also shows that many

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of the other recited species of xylanases included in these claims also lack the recited characteristics and does not show even a single species of xylanase which has the combinations of temperature and pH activities recited in claims 216 and 217. As such it is unclear what xylanases applicants intended to recite in claims 216 and 217. In view of the many contradictions and inconsistencies between the properties recited in claims 216 and 217 and the properties of the elected species of xylanase as shown in Table 6 of the specification, for the purposes of further examination claim 216 is interpreted as reciting making a composition comprising a xylanase "active under conditions comprising a temperature of at least 85°C or a basic pH of at least pH 11" and claim 217 is interpreted as reciting making a composition comprising a xylanase "active under conditions comprising a temperature of at least 80°C or a basic pH of at least pH 10.5" as such an interpretation would at least include the elected species.

Claim 219 is confusing in the recitation of wherein the xylanase comprises (a)(i) a nucleic acid...; (ii) a nucleic acid...; (b) a nucleic acid...; etc. as proteins do not comprise nucleic acids. Furthermore assuming that "wherein the xylanase comprises" was intended to recite wherein the xylanase is encoded by a nucleic acid comprising", the claim is needlessly

confusing as alternating between protein and nucleic acid multiple times when only a single one is necessary. For example part (a)(i) could be simply recited as "a nucleotide sequence having at least 50% sequence identity to SEQ ID NO:159". The other portions of claim 219 are similarly needlessly confusing.

Claim 219 is confusing as reciting many lists which include many members which are completely included within the scope of other members of the same list such that the additional recitation adds nothing to the scope of the claims except additional verbiage which only serves to make the claim needlessly long and confusing. These lists include that of part (a)(i) where every recited member of the list is fully within the scope of "having at least 50% identity to SEQ ID NO:159 (i.e., the first member of the list) and thus adds nothing to the claim, the list of part (b)(iv), the list of part (i) in which "a water soluble arabinoxylan" is fully within "an arabinoxylan", "hydrolyzing a xylan ... in a dough or bread product" is fully within "hydrolyzing a xylan ...", "hydrolyzing hemicelluloses ... in a wood, a wood product..." is fully within "hydrolyzing hemicelluloses", etc.; and the list of part (j).

Claim 219 is confusing in the recitation of parts (h)-(l) of the claim as part of the list of nucleic acids encoding a xylanase as these recite additional properties of a xylanase.

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Are these portions intended to be limitations of this claim? If yes then the portion identifiers should be removed. If not then these should be simply deleted from this claim. These portions of this claim include many confusing elements which the examiner has attempted to enumerate in the following. However it is noted that enumerating all of the problems in this claim is virtually impossible as the claim is so poorly worded and lengthy as to be incomprehensible. Part (h) of this claim is either redundant with the limitations of claim 216 or confusing as dependent on claim 217 as it makes it unclear if applicants intend the claim to recite xylanases active under the temperature conditions of 85°C or 80°C and pH conditions of pH 11 or pH 10.5. Most of the list of temperature conditions recited in parts (j) and (k) are confusing as the temperatures are lower than the temperature required by claims 216 and 217. The list of pH conditions recited in part (l) is confusing as the list includes the pHs required by claims 216 and 217 and thus it is unclear what if anything this recitation adds.

Claim 219 part (g) recites a nucleic acid comprising a sequence complementary to the nucleic acids of parts (a)-(f), however, these complementary sequences do not encode a xylanase and thus their recitation here makes no sense.

Claim 219 is indefinite in the recitation of "stringent conditions" as the specification does not define what conditions constitute "stringent". While part (b)(iii) of this claim defines particular conditions which are stringent, this recitation does not apply to parts (b)(i) and (ii) of this claim and there is nothing to suggest that other conditions would not also be included within the scope of this term as used in parts (b)(i) and (ii) and in the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of EQ ID NO:159, a sequence must be to be included within the scope of claim 219.

Claim 219 is confusing in the recitation of "(iii) the nucleic acid of (i) or (ii)" under part (d) as there is not part d)(i) or (d)(ii) and the previous portions of this part of the claim were reciting methods while this recites nucleic acids.

Claim 219 part (e) recites a nucleic acid of (a)-(d) encoding a xylanase but lacking a signal sequence or carbohydrate binding module. However nucleic acids cannot include a signal sequence or carbohydrate binding module.

Claim 219 part (f) recites a nucleic acid of (a)-(e) encoding a xylanase but having a heterologous sequence, wherein optionally the heterologous sequence comprises a heterologous

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signal sequence, carbohydrate binding module, catalytic domain or combination thereof. However nucleic acids cannot include a signal sequence, carbohydrate binding module, catalytic domain or combination thereof. Furthermore, the further recitation in this part of claim 219 which states "and optionally the heterologous signal sequence, carbohydrate binding module, or catalytic domain is derived from another xylanase or non-xylanase enzyme" appears to be unnecessary as all other xylanases and non-xylanase enzymes are within the scope of heterologous sequences.

Claim 220 is confusing in the recitation of "(d) a polypeptide having xylanase activity, wherein the polypeptide comprises an amino acid sequence encoded by a nucleic acid having a sequence as set forth in claim 219" as claim 219 does not recite nucleic acids.

Claim 220, part (e) is confusing as the method recited includes (iii) expressing the variant of the template sequence to generate a recombinant polypeptide" however the template sequence is an amino acid sequence. It is unclear how one expresses an amino acid sequence to produce a polypeptide. Part (e) of claim 220 is further confusing in the recitation of "optionally the polypeptide that retains xylanase activity under conditions comprising a temperature of at least about 70°C, 80°C

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or 90°C or more, and a basic pH of at least about pH 8.0, pH 8.5, pH 9, pH 9.5, pH 10, pH 10.5, pH 11 or more" as this is an incomplete statement and if "optionally the polypeptide retains xylanase activity under conditions comprising a temperature of at least about 70°C, 80°C or 90°C or more, and a basic pH of at least about pH 8.0, pH 8.5, pH 9, pH 9.5, pH 10, pH 10.5, pH 11 or more" was intended this is entirely unnecessary as reciting limitations already required by claims 216 or 217 from which this claim depends. Part (e) of claim 220 is further confusing in the recitation of "optionally the modifications ... " as the methods recited are methods of modifying nucleic acid not modifying amino acid sequences.

Claim 220 is confusing as reciting many lists which include many members which are completely included within the scope of other members of the same list such that the additional recitation adds nothing to the scope of the claims except additional verbiage which only serves to make the claim needlessly long and confusing. These lists include that of part (a) where every recited member of the list is fully within the scope of "having at least 50% identity to SEQ ID NO:160 (i.e., the first member of the list) and thus adds nothing to the claim, the list of part (i) in which "a water soluble arabinoxylan" is fully within "an arabinoxylan", "hydrolyzing a

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xylan ... in a dough or bread product" is fully within "hydrolyzing a xylan ...", "hydrolyzing hemicelluloses ... in a wood, a wood product..." is fully within "hydrolyzing hemicelluloses", etc.; and the list of parts (j-l); all of parts (c) and (f-p) which all appear to be fully encompassed within the scope of parts (a), (b) and (d) and thus completely unnecessary; Part (h) of this claim is either redundant with the limitations of claim 216 or confusing as dependent on claim 217 as it makes it unclear if applicants intend the claim to recite xylanases active under the temperature conditions of 85°C or 80°C and pH conditions of pH 11 or pH 10.5. Most of the list of temperature conditions recited in parts (j) and (k) are confusing as the temperatures are lower than the temperature required by claims 216 and 217. The list of pH conditions recited in part (p) is confusing as the list includes the pHs required by claims 216 and 217 and thus it is unclear what if anything this recitation adds.

Note: in view of the extremely numerous problems within claims 219 and 220 which make them virtually incomprehensible and unexaminable, for purposes of further examination claim 219 is interpreted as reciting the following:

"The method of claim 216 or 217 wherein the xylanase is encoded by a nucleic acid which

(a) comprises a nucleotide sequence having at least 50% sequence identity to SEQ ID NO:159

(b) will hybridize to SEQ ID NO:159 under stringent conditions or

(c) encodes a polypeptide having at least 50% sequence identity to SEQ ID NO:160".

and claim 220 is interpreted as reciting:

"The method of claim 216 or 217 wherein the xylanase has at least 50% sequence identity to SEQ ID NO:160".

It is believed that all other recitations of these claims are within the scope of this interpretation except with regard to the non-elected subject matter. If applicants intended these claims to include other subject matter, they should rewrite these claims in a fashion in which what they intend is understandable.

Claims 216 and 217 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to methods of making a composition comprising a xylanase by combining a genus of xylanases wherein the xylanase is active under conditions comprising a temperature of at least 80°C or 85°C or a basic pH of at least pH 10.5 or 11 with a carrier. The specification teaches the structure of only a few representative species of such xylanases. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of xylanase activity under conditions comprising a temperature of at least 80°C or 85°C or a basic pH of at least pH 10.5 or 11. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 216, 217, 219 and 220 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of making a composition comprising a xylanase by combining a xylanase having 90% identity to SEQ ID NO:160 with a carrier, does not reasonably provide enablement for any methods of making a composition comprising a xylanase by

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combining a xylanase having 50% identity to SEQ ID NO:160, encoded by a polynucleotide having at least 50% sequence identity to SEQ ID NO:159 or active under conditions comprising a temperature of at least 80°C or 85°C or a basic pH of at least pH 10.5 or 11 with a carrier polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 216 and 217 are directed to methods of making a composition comprising a xylanase by combining a genus of xylanases wherein the xylanase is active under conditions comprising a temperature of at least 80°C or 85°C or a basic pH of at least pH 10.5 or 11 with a carrier. Claims 219 and 220 as interpreted limit the methods to using a xylanase as defined above. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of xylanases necessary to practice the full scope of the claimed methods. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of

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modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the polypeptide of SEQ ID NO:160 encoded by SEQ ID NO:159.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass use of an enormous number of polypeptide variants of the polypeptide of SEQ ID NO:160 because the specification does not establish: (A) regions of the protein structure which may be modified without effecting xylanase activity; (B) the general tolerance of xylanases to modification and extent of such tolerance; (C) a rational and predictable

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scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including use of an enormous number of polypeptide variants of the polypeptide of SEQ ID NO:160. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 216, 217, 219, and 220 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Vehmaanpera et al. (US Patent 5,935,836) or Sung et al. (US Patent 5,759,840).

Vehmaanpera et al. and Sung et al. each teach alkalophilic and thermophilic xylanases, their use for biobleaching of wood pulp and methods of making compositions of these xylanases. The xylanases of Vehmaanpera et al. and Sung et al. maintain at least some activity at temperature conditions of 85°C or 80°C or pH conditions of pH 11 or pH 10.5. SEQ ID No:2 of Vehmaanpera et al. has 50% identity to residues 1-299 of SEQ ID NO:160 and SEQ ID NO:13 of Sung et al. has 64% identity to residues 27-214 of SEQ ID NO:160.

Claims 216 and 217 are rejected under 35 U.S.C. 102(b) as being anticipated by Bodie et al. (US Patent 5,437,992) or Casimir-Schenkel et al. (EP 473 545).

Bodie et al. and Casimir-Schenkel et al. each teach alkalophilic and thermophilic xylanases, their use for biobleaching of wood pulp and methods of making compositions of these xylanases. The xylanases of Bodie et al. and Casimir-Schenkel et al. maintain at least some activity at temperature conditions of 85°C or 80°C or pH conditions of pH 11 or pH 10.5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner

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can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652